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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 7,109,205. The application was filed on August 7, 2007, under 35 U.S.C. § 156. It is noted that applicant also filed applications for patent term extension for NDA 22-081 in U.S. Patent Nos. 5,703,017 (FDA-2008-E-0113), 5,840,722 (FDA-2008-E-0114), and 5,932,730 (FDA-2008-E-0103), pursuant to 37 CFR 1.785.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Raul Tamayo at (571) 272-7728 (telephone) or (571) 273-7728 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Martin L. Katz
Wood, Phillips, Katz, Clark & Mortimer
Citigroup Center, Suite 3800
500 West Madison Street
Chicago, IL 60661-2511

RE: LETAIRIS® (ambrisentan)
Docket No. FDA-2008-E-0110